

Notice of Non-Compliant Amendment (37 CFR 1.121)

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| Application No. | Applicant(s) |
| 10/533,847 | URNOV ET AL. |
| Examiner | Art Unit |
| Bradley L. Sisson | 1634 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

The amendment document filed on 19 January 2010 is considered non-compliant because it has failed to meet the requirements of 37 CFR 1.121 or 1.4. In order for the amendment document to be compliant, correction of the following item(s) is required.

THE FOLLOWING MARKED (X) ITEM(S) CAUSE THE AMENDMENT DOCUMENT TO BE NON-COMPLIANT:

- ☐ 1. Amendments to the specification:
- ☐ A. Amended paragraph(s) do not include markings.
 - ☐ B. New paragraph(s) should not be underlined.
 - ☐ C. Other _____.
- ☐ 2. Abstract:
- ☐ A. Not presented on a separate sheet. 37 CFR 1.72.
 - ☐ B. Other _____.
- ☒ 3. Amendments to the drawings:
- ☐ A. The drawings are not properly identified in the top margin as "Replacement Sheet," "New Sheet," or "Annotated Sheet" as required by 37 CFR 1.121(d).
 - ☐ B. The practice of submitting proposed drawing correction has been eliminated. Replacement drawings showing amended figures, without markings, in compliance with 37 CFR 1.84 are required.
 - ☒ C. Other See Continuation Sheet.
- ☐ 4. Amendments to the claims:
- ☐ A. A complete listing of all of the claims is not present.
 - ☐ B. The listing of claims does not include the text of all pending claims (including withdrawn claims)
 - ☐ C. Each claim has not been provided with the proper status identifier, and as such, the individual status of each claim cannot be identified. Note: the status of every claim must be indicated after its claim number by using one of the following status identifiers: (Original), (Currently amended), (Canceled), (Previously presented), (New), (Not entered), (Withdrawn) and (Withdrawn-currently amended).
 - ☐ D. The claims of this amendment paper have not been presented in ascending numerical order.
 - ☐ E. Other: _____.
- ☒ 5. Other (e.g., the amendment is unsigned or not signed in accordance with 37 CFR 1.4):
See Continuation Sheet

For further explanation of the amendment format required by 37 CFR 1.121, see MPEP § 714.

TIME PERIODS FOR FILING A REPLY TO THIS NOTICE:

- Applicant is given no new time period if the non-compliant amendment is an after-final amendment or an amendment filed after allowance. If applicant wishes to resubmit the non-compliant after-final amendment with corrections, the entire corrected amendment must be resubmitted.
- Applicant is given one month, or thirty (30) days, whichever is longer, from the mail date of this notice to supply the correction, if the non-compliant amendment is one of the following: a preliminary amendment, a non-final amendment (including a submission for a request for continued examination (RCE) under 37 CFR 1.114), a supplemental amendment filed within a suspension period under 37 CFR 1.103(a) or (c), and an amendment filed in response to a Quayle action. If any of above boxes 1. to 4. are checked, the correction required is only the corrected section of the non-compliant amendment in compliance with 37 CFR 1.121.

Extensions of time are available under 37 CFR 1.136(a) only if the non-compliant amendment is a non-final amendment or an amendment filed in response to a Quayle action.

Failure to timely respond to this notice will result in:

Abandonment of the application if the non-compliant amendment is a non-final amendment or an amendment filed in response to a Quayle action; or

Non-entry of the amendment if the non-compliant amendment is a preliminary amendment or supplemental amendment.

/Bradley L. Sisson/
Primary Examiner, Art Unit: 1634

Continuation of 3(c) Other:

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because: The lettering is not of proper size, uniform density, and well-defined in Figure(s) 1, 3A, 3B, and 4-6. See 37 CFR 1.84 (l) and (p)(1) - (5) ("Numbers, letters, and reference characters must measure at least .32 cm (1/8 inch) in height.") Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

INFORMATION ON HOW TO EFFECT DRAWING CHANGES

Replacement Drawing Sheets

Drawing changes must be made by presenting replacement sheets which incorporate the desired changes and which comply with 37 CFR 1.84. An explanation of the changes made must be presented either in the drawing amendments section, or remarks, section of the amendment paper. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(c). A replacement sheet must include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of the amended drawing(s) must not be labeled as "amended." If the changes to the drawing figure(s) are not accepted by the examiner, applicant will be notified of any required corrective action in the next Office action. No further drawing submission will be required, unless applicant is notified.

Identifying indicia, if provided, should include the title of the invention, inventor's name, and application number, or docket number (if any) if an application number has not been assigned to the application. If this information is provided, it must be placed on the front of each sheet and within the top margin.

Annotated Drawing Sheets

A marked-up copy of any amended drawing figure, including annotations indicating the changes made, may be submitted or required by the examiner. The annotated drawing sheet(s) must be clearly labeled as "Annotated Sheet" and must be presented in the amendment or remarks section that explains the change(s) to the drawings.

Timing of Corrections

Applicant is required to submit acceptable corrected drawings within the time period set in the Office action. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDONMENT of the application.

If corrected drawings are required in a Notice of Allowability (PTOL-37), the new drawings MUST be filed within the THREE MONTH shortened statutory period set for reply in the "Notice of Allowability." Extensions of time may NOT be obtained under the provisions of 37 CFR 1.136 for filing the corrected drawings after the mailing of a Notice of Allowability.

Continuation of 5 Other:

As set forth under 37 CFR 1.111(b): "The reply by the applicant or patent owner must be reduced to a writing which distinctly and specifically points out the supposed errors in the examiner's action and must reply to every ground of objection and rejection in the prior Office action."

At paragraph 7 of the Office action the aspect of the specification disclosing but a single amino acid sequence, and no nucleotide sequence, when the claims are directed to nucleic acids in an array, was developed. A review of the disclosure fails to find where this aspect of the non-satisfaction of the written-description requirement was addressed.

At paragraphs 12-13 of the Office action the issue of the specification not describing how one would be able to distinguish between those nucleic acids that are useful from those that are not, has not been found to be addressed. The response has not been found to address the aspect of possession- actual or constructive, of the claimed arrays. It is noted that at page 9 of the response applicant asserts: "the polynucleotides of the array can and will differ tremendously from each other and between arrays."

At page 12 of the Office action the issue of the specification not enabling the use of the arrays of DNA comprising "accessible regions" in any method that has utility under 35 USC 101 was developed. While applicant does address the enablement-based rejection as it pertains to the making of the arrays, it has not been found to enable the use of the array in any method that has utility under 35 USC 101, when, as noted above, "the polynucleotides of the array can and will differ tremendously from each other and between arrays."